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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. ELIZABETH HOLMES and RAMESH "SUNNY" BALWANI, Defendants.	Case No. 18-CR-258 EJD UNITED STATES' MOTION TO EXTEND DEADLINE BY WHICH TO COMPLY WITH COURT'S NOVEMBER 5, 2019, ORDER Date: January 13, 2020 Time: 10 a.m. Courtroom: 4, 5th Floor

NOTICE OF MOTION AND MOTION

TO ALL PARTIES AND THEIR COUNSEL OF RECORD:

PLEASE TAKE NOTICE that on January 13, 2020, at 10:00 a.m., or as soon thereafter as counsel may be heard, in Courtroom 4, 5th Floor, of the United States District Court for the Northern District of California, Robert F. Peckham Federal Building & U.S. Courthouse, 280 South 1st Street, San Jose, California 95113, the United States of America will and hereby does move for an order extending the time for the government to complete production of documents responsive to the Court's November 5, 2019, Order.

This motion is based upon the following Memorandum of Points and Authorities, the December 30, 2019 Declaration of Robert S. Leach, oral argument, the pleadings and exhibits on file, and any other evidence the Court may consider.

DATED: December 30, 2019

Respectfully submitted,

ADAM A. REEVES
Attorney for the United States
Acting Under Authority Conferred
by 28 U.S.C. § 515

ROBERT S. LEACH
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MEMORANDUM OF POINTS AND AUTHORITIES

The government respectfully requests an extension of time to complete production of documents responsive to the Court's November 5, 2019, Order. Despite the government's best efforts, its lack of control over the documents at issue has made it impossible to obtain the documents from FDA quickly enough to meet the current deadline.

On November 5, 2019, the Court issued an Order Granting Motion to Compel production of documents held by FDA and CMS responsive to six categories identified by the defense:

1. Any and all correspondence or communications regarding Theranos between the government and John Carreyrou, *The Wall Street Journal*, or their employees, agents, or counsel, and all government documents, communications, correspondence, notes, or recordings (including intra-agency and/or inter-agency correspondence) regarding same;
2. Any and all government documents, communications, correspondence, notes, or recordings (including intra-agency and/or inter-agency communications) regarding Theranos' Clinical Laboratory Improvement Amendments ("CLIA") compliance during the time period of the charged conspiracies, including but not limited to those that concern the 2015 CLIA survey of Theranos;
3. Any and all correspondence or communications regarding Theranos between the government and any clinical laboratory company or association affiliated with clinical laboratories (including but not limited to LabCorp, Quest Diagnostics, and the American Clinical Lab Association), or their employees, agents, or counsel, and all government documents, communications, correspondence, notes, or recordings (including intra-agency and/or interagency correspondence) regarding same;
4. Any and all government documents, communications, correspondence, notes, or recordings (including intra-agency and/or inter-agency communications) regarding the FDA's determination of the type of FDA approval required for Theranos' proprietary technology;
5. Any and all FBI 302s or other agency ROIs memorializing government communications with witnesses, and all government documents, communications, correspondence, notes,

or recordings (including intra-agency and/or inter-agency correspondence) regarding same; and

6. Any and all government documents, communications, correspondence, notes, or recordings (including intra-agency and/or inter-agency communications) regarding the 2013 CLIA survey of Theranos.

ECF No. 174. The Court found "the Prosecution has knowledge of and access to the at-issue documents" and "order[ed] the Prosecution to produce the documents discussed below as part of their Rule 16 obligation, and to assist the Agencies however possible to ensure the timely production of documents." *Id.* at 3. The Court also ordered "that FDA shall run searches of all of its custodians' documents using the following terms: 'LDT,' 'Laboratory Developed Test,' 'Theranos,' 'fingerstick' or 'finger stick,' and 'nanotainer' . . . [and] shall produce any responsive documents returned by these searches." *Id.* at 4. The Court ordered FDA and the government to complete the production of documents by December 31, 2019. *Id.*

Although FDA had previously collected documents from certain custodians using the search terms "Theranos" and "nanotainer," it had not collected documents from custodians using the search terms "LDT," "Laboratory Developed Test," "fingerstick," or "finger stick."[1] *See* Declaration of AUSA Robert S. Leach in Support of United States' Motion to Extend Deadline by Which to Comply with Court's November 5, 2019, Order ¶ 3, dated December 31, 2019 ("Leach Decl."), filed concurrently. The Court's order thus required FDA to perform a new document collection.

That collection process takes substantial time. Indeed, at the November 4, 2019 hearing on the motion to compel, an FDA lawyer emphasized:

> if we had to go back to our original search of the over 80 custodians that have been searched so far and add new search terms like fingerstick or [LDT], that would take quite some time because for the former employees those searches are out of our hands. Those are done by our office of information management staff, and I think we were recently told that it's at least six weeks to do a search of a former employee's files. So what Ms. Martinez-Resly was talking about is if we add those search terms to the currently collected documents, which I believe is hundreds of thousands of pages, that could be

[1] There was good cause for this. The defense's six categories were all specific to "Theranos." None of the six categories mentioned the word "LDT" or "Laboratory Developed Test," and the defendants' motion to compel did not make a single reference to those terms. *See generally* ECF No. 67. Using the term "LDT" and "fingerstick" to collect documents returns a large number of nonresponsive documents.

> done with the software that we have now. If we're talking about researching, especially with respect to those former employees, I don't know that we would be able to meet an end-of-the-year deadline.

Leach Decl. Ex. A.

Since November 5, the government has worked diligently to produce documents in response to the Court's order.

On or about November 8, 2019, in conformance with the Court's Order, the government met and conferred with the defense about the search terms FDA was to use to search for and collect potentially responsive documents. Leach Decl. ¶ 3. Counsel for the defense suggested "Laboratory-Developed Test," or "Lab-developed test," or "finger stick," or "finger-stick," or "Holmes" be run, in addition to the terms ordered by the Court and the following terms that FDA had previously advised had been run for certain custodians: Balwani OR "Elizabeth w/3 Holmes" OR eholmes OR eholmes2003 OR eholmes@theranos.com OR Theranos OR "TSPU" OR "TSCD" OR Nanotainer OR "Capillary Tubes" OR "Nanotainer Tubes" OR "Lithium-Heparin" OR "CTN" OR "K2EDTA" OR "K152647" OR "K152965" OR "K152971" OR "Q151162" OR "Q151964" OR "Q160388" OR "Q160470" OR "K143236" OR "CW150009" OR "TLAS" (collectively, "Collection Terms"). *Id.*

During the week of November 18, 2019, undersigned counsel and AUSA Jeff Schenk traveled to Silver Spring, Maryland, to meet personally with FDA representatives to discuss a plan for FDA's production.[2] *Id.* ¶ 4.

On November 22, 2019, the government met and conferred further with the defense. *Id.* ¶ 5. The government proposed a plan that would address issues of redaction and duplication that generated objections to prior productions. *Id.* Specifically, the government proposed that FDA be ordered to produce documents responsive to the Collection Terms ("Ordered FDA Documents") to DOJ without any review for trade secret, confidential commercial information, or privileged information, notwithstanding certain statutory and regulatory prohibitions on FDA doing so. *Id.*; *see, e.g,* 21 U.S.C.

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[2] That week, AUSA Schenk and undersigned counsel also met in Washington, DC with the Deputy General Counsel and another attorney from CMS to discuss a plan for production of documents. Undersigned counsel also traveled to Baltimore to personally review potentially responsive CMS documents. The government anticipates completing its production of CMS documents in response to the motion to compel on the deadline of December 31, 2019. Leach Decl. ¶ 4.

§§ 331(j), 360j(c). The government further proposed that it would produce documents responsive to the six categories to defendants without a specific review for trade secret, confidential commercial information, or privileged information, subject to an additional protective order providing for "attorney's eyes only" protection and later redaction for documents produced to defendants with trade secret and confidential commercial information. *Id.*

The government also requested that the defense identify the custodians it viewed as most significant, so the government could prioritize those custodians. *Id.* ¶ 5. On November 27, 2019, defendant Balwani identified 22 lay custodians, in addition to the FDA-Criminal Investigation case agent, George Scavdis, assigned to the matter. *Id.* ¶ 6. Defendant Balwani also insisted that 55 additional custodians' documents be electronically searched. *Id.*

On December 1, 2019, the government submitted a Stipulation and [Proposed] Order Regarding Certain FDA Documents, which, when approved by the Court on December 2, directed FDA to produce the Ordered FDA Documents to DOJ notwithstanding the provisions of 21 U.S.C. §§ 331(j) and 360j(c). ECF Nos. 183 & 184. Subsequently, the government negotiated with defendant Balwani agreeable "attorney's eyes only" modifications to the protective order, which were submitted on December 23, 2019, and approved on December 27, 2019. ECF Nos. 212 & 214.

On December 6, 2019, FDA produced to DOJ approximately 2.589 GB of Outlook 365 email data from three custodians: J.K., L. Ll., and K.W. The government completed a review of this material for responsiveness to the six categories on December 18 and anticipates producing approximately 2,719 documents on December 31. Leach Decl. ¶ 7.

On December 19, 2019, FDA produced to DOJ approximately 91.37 GB of Outlook 365 email data from twelve additional custodians (11 of whom were identified by defendant Balwani as a priority): J.F., C.L., I.P., J.S., J.D., K.S., K.K., K.H., M.C., S.M., U.S., and Y.C.. Based on its review to date, the government anticipates producing approximately 136,092 documents on December 31. *Id.* ¶ 8.

The government anticipates that on January 3, 2020, it will receive from FDA up to 350GB of Outlook 365 email data from up to 12 custodians. The government is making arrangements to have that volume reviewed for a further production to the defense by the week of January 13, 2019. *Id.* ¶ 9.

Since November 5, undersigned counsel has exchanged at least 100 emails and participated in at least a dozen phone calls with FDA counsel in an effort to achieve compliance with the Court's order. *Id.* ¶ 10. The government has continually offered resources and assistance to FDA to accelerate the process, including, for example, additional personnel and/or funds. *Id.*

Based on the government's extensive dialogue with counsel for FDA, the government understands there are substantial technological and other limits on FDA's ability to quickly collect documents from its custodians that additional personnel or funds will not address. *Id.* ¶ 11. In addition to hardware and software processing limitations that allow FDA to process one custodian a day, at best, FDA has contractual limits with its email and digital investigations software providers that cap how much data can be extracted simultaneously. *Id.* FDA is in the process of addressing these caps. The process of restoring archived data of former employees is even more time consuming. *Id.* The government also understands that FDA is devoting virtually all available Office of Chief Counsel eDiscovery and information technology resources to collecting documents for this matter, notwithstanding demands from other pending cases, and indeed is requesting additional resources from other parts of FDA beyond the Office of Chief Counsel. *Id.*

For these reasons, the government is unable to meet the December 31, 2019, deadline set by the Court and respectfully requests additional time to comply. *Id.* ¶ 12. The government has consulted at the highest levels of FDA about when it can complete its collection and delivery to DOJ. *Id.* As describe above, defendant Balwani has identified 77 custodians (excluding the case agent). Defendant Holmes and FDA have identified an additional 11 for a total of 88. *Id.* In the interest of speed, FDA is implementing a tiered-approach where it collects electronically via remote collection Outlook 365 emails for current FDA personnel, electronic documents for current FDA custodians from network drives, documents from stand-alone devices, and documents from FDA databases, as well as hard copy documents from FDA personnel and archived documents from former FDA personnel. *Id.* FDA is providing data to DOJ on a rolling basis and currently expects, using its best efforts, that it can provide all collected data to DOJ by April 30, 2020. *Id.*

This date presumes FDA will conduct a manual search for approximately 23 custodians; i.e., under the supervision of FDA attorneys, 23 custodians will self-collect documents. *Id.* ¶ 12. The

government and FDA assess these 23 individuals had minimal role in Theranos matters and are competent to conduct a manual search of their own files under the supervision of FDA attorneys.[3] *Id.* The Court has ordered the parties to meet and confer on this issue, but the defense appears to insist that any form of manual search is insufficient. The sole support for the defense's argument is a seven-year old, out-of-district civil case involving FOIA that Magistrates in the Northern District have declined to follow. *National Day Laborer Org. Network v. U.S. Immigration & Customs Enforcement Agency*, 877 F. Supp. 2d 87 (S.D.N.Y. 2012). *But see T.D.P. v. City of Oakland*, 2017 WL 3026925, at *4 (N.D. Cal. July 17, 2017) (Beeler, M.J.); *Bothwell v. Brennan*, 2015 WL 6689387, at *5 (N.D. Cal. Nov. 3, 2015) (Corley, M.J.).

There is no reason to believe a manual search for a minority of marginally relevant custodians is insufficient. First, the parties have agreed on the collection search terms that must be run. Thus, custodians will not exercise discretion on what to provide. Second, at least 10 of the manual custodians are attorneys in FDA's Office of Chief Counsel, who by virtue of training and experience are capable of following specific instructions for the search; indeed, many have done so in prior cases. Leach Decl. ¶ 12. Finally, the defense cites no decision where a court has held the government in meeting its Rule 16 obligation must employ remote electronic collection techniques that remove custodians from the collection process. There is good reason for this. "FOIA provides a 'statutory right of public access to documents and records' held by federal government agencies." *Citizens for Responsibility & Ethics in Washington v. U.S. Dep't of Justice*, 602 F. Supp. 2d 121, 123 (D.D.C. 2009) (quoting *Pratt v. Webster*, 673 F.2d 408, 413 (D.C. Cir. 1982)). The scope of civil discovery may extend to "any nonprivileged matter that is relevant" and "need not be admissible in evidence to be discoverable." Rule 16, by contrast, is limited to items "material to preparing the defense." Fed. R. Crim. P. 16(a)(1)(E)(i). Given the breadth of the materials already produced by FDA and the government and the use of a remote

[3] The government also had Agent Scadvis self-collect documents from his devices. Agent Scadvis had no involvement with Theranos prior to the criminal investigation. He had no reason to possess documents responsive to the six categories, other than documents he created or received during the investigation. Given his involvement in the criminal investigation, he is fully capable of manually searching his files for responsive information under the supervision of the prosecutors on this matter. Leach Decl. ¶ 14.

electronic search for 65 of the 88 custodians identified, there is no reason to think material information will escape the manual search.

Aside from the disagreement addressed above, the government has acceded to virtually all requests from the defense regarding the scope of the search for FDA documents. Accommodating those requests has expanded the scope of the collection efforts beyond what was previously presented to the Court, slowing the process further.

The government recognizes the Court has held multiple hearings on this motion and does not lightly request additional time. The motion to compel was presented as limited to six "narrow categories" (ECF No. 67 at 1:22, 2:26, 3 n.3, 14:10, 25:25). The defendants' discovery request has now morphed into a demand for an electronic search encompassing scores of custodians and using broad search terms. The government has devoted, and will continue to devote, all available resources to this issue, but lacks control over critical steps in the process and needs additional time to comply.

DATED: December 30, 2019

Respectfully submitted,

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